IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	)	**REDACTED PUBLIC VERSION** C.A. No. 21-1694-JLH
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	)	

FINCH/UMN'S BRIEF IN OPPOSITION TO
FERRING'S MOTIONS FOR SUMMARY JUDGMENT AND DAUBERT MOTION

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Party / Witness Key

Abbreviation	Party
UMN	University of Minnesota
Finch	Finch Therapeutics, Inc., Finch Therapeutics Group, Inc. and UMN (unless otherwise noted)
Ferring	Ferring Pharmaceuticals Inc. and Rebiotix Inc. (unless otherwise noted)

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I. Introduction

Seemingly trepidatious about the right to trial by jury enshrined by the Constitution, Ferring asks the Court to resolve nearly every issue in the case prior to trial, through summary judgment or *Daubert*. Ferring asks the Court to resolve more than a dozen heavily contested primary issues, and numerous additional sub-issues, as a matter of law—including infringement, validity, patentable subject matter, willful infringement, copying and damages—at times providing little to no explanation for its arguments. This indiscriminate, blunderbuss approach, which when combined with the governing page limits leaves little room for Finch to fully respond to all Ferring's arguments, is not a proper use of the summary judgment (or *Daubert*) process. *Nox Med. EHF v. Nate's Neurology Inc.*, 2018 WL 845635, at *10 (D. Del. Feb. 13, 2018) (denying summary judgment with limited exception "because Plaintiff raises so many issues that most of them are at best cursorily briefed."). These issues involve numerous material fact disputes that cannot be resolved on summary judgment, and at times re-hash arguments the Court previously rejected. And Ferring's only-cursorily-explained requests to exclude large swaths of Finch expert opinion misunderstands the limited nature of *Daubert* exclusions. Ferring's motion should be denied.

II. The Court Should Deny Ferring's Partial Motion of No Copying/Willfulness

A. Ferring's Partial Motion For No Copying Should be Denied

Ferring's request is solely based on Ferring's assertion that Finch failed to establish a sufficient nexus between the materials Ferring copied and "the novel elements of the claim." Br. 3. Not so.

For the UMN patents,[1] the nexus is clearly demonstrated by materials Ferring took from

[1] A further discussion of Ferring's egregious copying of UMN's and Finch's inventions is set forth in Finch's summary judgment brief. D.I. 262 at 5–8.

UMN and used in developing REBYOTA, all of which are *per se* tied directly to the patent claims. ***First***, during her purported 2011 evaluation of UMN's technology, Rebiotix's Lee Jones obtained the then-confidential ***provisional patent application*** that led to ***the UMN Patents asserted in this case***, which she retained to this day. D.I. 265, Ex. 12 at UMN_0279932–952; D.I. 265, Ex. 20. There is no question this application shows the "novel aspects" of the claims, as it includes a near verbatim version of the patented embodiments. *Id.*; Ex. 64 ¶ 1375; Ex. 65 §§ VIII.E and IX (discussing Examples 1–3). ***Second***, Ms. Jones was also provided the inventors' confidential protocol for making the patented composition, which is repeated ***verbatim*** in Example 3 of the specification, which Ferring concedes embodies the claims. Br. §III.E; D.I. 265, Ex. 14; Ex. 64 ¶¶ 969, 1375; Ex. 65 ¶¶ 101, 151. ***Third***, Ms. Jones was provided in-person demonstrations of how the claimed compositions are made. Ex. 66 at 407. ***Fourth***, Ms. Jones obtained the inventors' 2012 paper, which provides the processing protocol set forth as the patents' Example 4. Br. Ex. 15; Ex. 67; Ex. 64 ¶ 969, 1376, 1388. ***Fifth,*** Ms. Jones also took multiple other UMN-confidential documents describing the patented inventions, including an evaluation of the patented inventions and business opportunities (Br. Ex. 12 at FER_RBX01092755–759), a detailed description of the inventions' "Protectability" and "Technical Merit" (D.I. 265, Ex. 15 at FER_RBX02724822–823), and other information concerning their goals and opportunities (D.I. 265, Ex. 13).

Finch's expert Dr. Benson confirmed the obvious nexus to the UMN claims. Ex. 64 ¶¶ 59 (nexus summary); 1382 (patent application and other UMN work product relate to inventions' novel aspects); 1375 (confidential provisional patent application); 969 (confidential protocol is Example 3; 2012 paper is Example 4); 1388 (similar); *see also* Ex. 65 ¶¶ 101, 151 (Example 3 described asserted claims). Additional fact testimony from the inventors confirms the nexus as well. Ex. 68 at 139:19–141:9, 144:9–145:3; Ex. 69 at 25:15–27:22, 81:25–85:1; Ex. 70 at288:5–

20; Ex. 64 ¶¶ 988–90, 1424–31.

There is also no question that Ferring copied UMN's materials into REBYOTA. Dr. Benson confirmed all claim elements (described in the copied materials) are present in REBYOTA, which was developed ***after*** Ms. Jones gained access to UMN's patented protocol, and ***while*** she was circulating it internally to REBYOTA developers. Ex. 64 ¶¶ 1374–79, 1388; Br. Ex. 15 (Ms. Jones brazenly stating that the inventors' 2012 paper—which contains verbatim descriptions of the invention used in the UMN patents—was ***"[v]ery helpful"***); Ex. 67 (2012 paper ***gave Rebiotix a "leg up"***); Ex. 71 (Ms. Jones forwarding UMN analysis (JONESL00004307) to Barbara Nelsen, the ***Chief Technology/Commercialization Officer,*** for developing REBYOTA). Rebiotix also went to lengths to conceal its copying.[2] And after the UMN patents issued, [redacted], which Ferring had copied from UMN. Ex. 62; Br. Ex. 11 at 164:6–165:9; Ex. 64 ¶ 59, 1379, 1388; D.I. 262, App'x A. Ferring was also aware of the Borody provisional application in 2012, ***before*** the REBYOTA formulation was finalized in 2013, and identified him as a pioneer in the field of FMT. *E.g.*, D.I. 265, Ex. 23 at 13; Ex. 75 at 300:2–12; Ex. 76. Per Dr. Benson, that evidence is directly tied to the Borody claims, which are explicitly found in REBYOTA. Ex. 64 ¶¶ 1276–78, 1282.

The above is precisely the type of nexus evidence sufficient to present copying to the jury.

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[2] For example, Ms. Jones copied the UMN inventors' business plan into her own, but hid that from UMN. *Compare* D.I. 265, Ex. 13 at UMN_0120277 (UMN), *with* D.I. 265, Ex. 18 at JONESL00003190 (Jones); Ex. 64 ¶¶ 1375–76, 1379; Ex. 73 at UMN_0017940. Later, she created an internal business plan crediting the UMN inventors with "inspir[ing]" her and "creat[ing] a simple solution to the horrible problem of debilitating diarrhea" caused by CDI. Ex. 74 at JONESL00003142. Fearing discovery, she later removed that passage. *Id.* at JONESL0003118; JONESL00003116 ("[redacted] Ex. 75 at 221:21–222:9.

See Liqwd, Inc. v. L'Oreal USA, Inc., 941 F.3d 1133, 1138 (Fed. Cir. 2019) (infringer copied then-confidential patent application established nexus); *Medtronic, Inc. v. Teleflex Innovations S.a.r.l.*, 70 F.4th 1331, 1340 (Fed. Cir. 2023) ("Evidence of access and substantial similarity ***is*** evidence of copying."); *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1347–48 (Fed. Cir. 2013) (access to patented method can be evidence of nexus). At the least, material fact disputes exist warranting denial of this motion. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016) (en banc); *cf.* Ferring case, *Dako Denmark A/S v. Leica Biosystems Melbourne Pty Ltd.*, 662 F. App'x 990, 997–98 (Fed. Cir. 2016) (non-precedential) (no nexus after trial on the merits).

The crux of Ferring's argument is its incorrect assertion that Dr. Benson "admitted" he "fails to show a nexus." Br. 4. That is baseless. Ferring's support consists of his testimony that (1) ***one*** aspect of ***one*** document does not repeat what the claims say verbatim. (Br. Ex. 11 at 137:8–138:24); (2) another document was "evidence of" the claims (*id*. at 159:23–160:4); and (3) REBYOTA does not use "[t]he ***exact*** process" set forth in the inventors' 2012 paper (*id*. 163:16–22 (discussing Br. Ex. 15))—none of which undermines his opinions on nexus. And Dr. Benson's lack of recall of "what exactly" Ferring copied from Borody (Br. Ex. 11 at 223:7–9) does not negate Rebiotix's possession of the Borody provisional or Dr. Benson's opinions connecting that to the Borody claims and how they are embodied by REBYOTA. Ex. 64 ¶¶ 1276–78, 1282.[3] That the claims did not issue until later (Br. 4–5) is irrelevant; senior executives at Ferring copied embodiments of the claims, which it lauded internally.

B. Ferring's Motion Of No Willfulness Should Be Denied

In two sentences, Ferring summarily concludes that there is no evidence of willful

[3] Ferring's references to efforts to license the Borody patents is a red herring; that is relevant to secondary considerations other than copying, *e.g.*, licensing.

infringement. That is wrong: Ferring copied the patented inventions, then studied the asserted patents after they issued knowing REBYOTA was copied from the descriptions therein, all the while continuing to market and sell REBYOTA unabated without determining it does not infringe. For the UMN Patents, as discussed above, Ms. Jones absconded with UMN's confidential materials that describe the patented inventions and used that as the basis for her own company and competing product, REBYOTA, unbeknownst to the inventors or UMN. Ex. 78 ¶ 54; Ex. 71; Ex. 67; D.I. 265, Ex. 18; Ex. 75 at 224:5–16. And Ferring admits it has been aware of the UMN patent claims since they issued. D.I. 262 at 6 (citing D.I. 265, Ex. 21 at 22:15–24:24, Ex. 22 at FER_RBX02848241); D.I. 265, Ex. 23 at 14. And for the Borody patents, Ferring copied the Borody patents, referred to Borody as a pioneer and and knew Finch—which acquired his patented technology—was "a competitor to watch closely." Ex. 78 ¶ 58; Ex. 79 at FER_RBX02877378; *see also* Ex. 80; Ex. 81 (discussing Dr. Borody's intellectual property in 2014); D.I. 252 at 13 (pre-suit awareness of Borody patents). Ferring repeatedly confirmed its need to license the UMN technology. D.I. 265, Ex. 24 at UMN_0017939–940; *id.*, Ex. 26 at FER_RBX02798547; *id.*, Ex. 18 at JONESL00003189, 192D.I. 262 at 7 (citing deposition testimony).[4]

And, critically, Ferring made ***no effort*** to change REBYOTA. Ex. 82 at 24 (Ferring "unaware of any attempt to design around the patents in suit"); Ex. 77 at 273:17–22; Ex. 64 ¶ 1384 n.14. That is egregious: Ferring literally copied the patented inventions from the patent applications for the patents-in-suit, but continued business as usual, pushing its product through the FDA to obtain a [redacted]" to [redacted]

[4] [redacted]. D.I. 262 at 7–8 (citing D.I. 265, Ex. 30 at FER_RBX02840624, 649, 680–681, 745, 748; D.I. 265, Ex. 31 at FER_RBX02738175–176, 251, 254, 403).

[redacted]" Ex. 83 at FER_RBX02067937; Ex. 84 at FER_RBX02021578; Ex. 85; Ex. 86. This forced Finch to discontinue developing its competing product and layoff its workforce. Ex. 87. That is more than sufficient to establish willfulness. *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 492 (Fed. Cir. 2019). Ferring's remaining arguments are essentially identical to its "no copying" arguments and are incorrect for the reasons as above. Br. 7; *supra* § II.A.[5] At best, material fact disputes exist, requiring denial.

III. The UMN Patents Fully Comply With 35 U.S.C. § 112

A. Ferring's Request to Find the *Markush* Group Improper Should Be Denied.

Repeating an argument it raised during *Markman*, Ferring asks the Court to find the UMN patents' Markush group "is an improper Markush group." *Compare* Br. 7, *with* D.I. 91 at 54–56, 58; D.I. 134; D.I. 145. Ferring's request is legally improper and factually wrong.

Ferring's argument—focusing on whether the Markush group satisfies the MPEP (which does not carry the force of law, *see Racing Strollers, Inc. v. TRI Indus., Inc.*, 878 F.2d 1418, 1422 (Fed. Cir. 1989))—misunderstands the issue before this Court. As the Federal Circuit explained, "[o]ur task involves determining the definiteness of a claim, . . . ***not evaluating the propriety of Markush language***." *Lexington Luminance LLC v. Amazon.com Inc.*, 601 F. App'x 963, 968 (Fed. Cir. 2015); *see also Microsource, LLC v. Eco World Grp., LLC*, 587 F. Supp. 3d 770, 831 (N.D. Iowa 2022) (same).[6] Ferring tacitly acknowledges the proper question is whether the claims are

[5] Contrary to Ferring's assertions, the evidence does not solely "predate the issuance" of the patents (*id.*); regardless, a finding of willfulness based on pre-issuance evidence is warranted here as Ferring engaged in "particularly egregious behavior." *Chimie v. PPG Indus., Inc.*, 218 F.R.D. 416, 421–22 (D. Del. 2003).

[6] Ferring's cases involve appeals of examiner rejections in prosecution, not validity determinations in a patent infringement suit, and involve issues not present here. *In re Kiely*, 2022 WL 2062163, at *2 (Fed. Cir. June 8, 2022) (considering "the issue of indefiniteness"); *In re Hass*, 141 F.2d 122, 125–26 (C.C.P.A. 1944) (considering an "artificial genus").

"invalid ***as indefinite***" (Br. 9–10), but never explains why a POSA would not understand them. *See generally* Br. 7–10. To the contrary, Ferring admits the Markush group is readily understood: "***[i]t is undisputed that the Markush group is met if*** there is at least one bacteria present from at least six of the enumerated classes." Br. 8. That is the end of the inquiry.

Consistent with Ferring's admission, the Markush group informs a POSA with reasonable certainty about the scope of the claims: the fecal extract must contain ***at least six of the ten recited classes of bacteria***. D.I. 265, Ex. 5, 5:1–7, 7:15–64; D.I. 265, Ex. 6, 5:19–29, 7:37–8:19; D.I. 262, App'x A ('012 cl. 1, '914 cls. 4, 9). It was the ***Examiner*** who added the Markush group language, which is "highly relevant" evidence of definiteness. *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1348 (Fed. Cir. 2022); *see* Ex. 65 ¶¶ 109, 204. And Ferring's experts readily applied the Markush claim language in their opinions. Ex. 88 ¶ 139; Ex. 89 ¶¶ 101–105; *Guangdong v. ITC*, 936 F.3d 1353, 1361–62 (Fed. Cir. 2019) ("application of these terms by the parties' experts" supports definiteness).

Expert testimony also requires denying Ferring's motion. As Dr. Schloss opined, "there is nothing unclear" about the claim's scope. Ex. 65 ¶¶ 202–05. And the sole basis for Dr. Treangen's contrary opinion relies on conclusory suggestions of overbreadth. Ex. 90 at 360:14–19, 351:23–352:12; *see also* Ex. 91 ¶ 104 (conclusory opinion). But "a claim is not indefinite just because it is broad," *Niazi*, 30 F.4th at 1347, and conclusory opinions cannot support summary judgment, *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019). Ferring has not met its burden, but at a minimum, the jury must resolve these fact disputes. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1371 (Fed. Cir. 2017) (for definiteness, "what a [POSA] would understand . . . is a question of fact").

Even if the issue were whether the Markush group complies with the MPEP, it clearly does.

The classes of bacteria recited in the Markush group share both a single structural similarity and common use. The claimed bacterial classes "belong to the same . . . art-recognized class." MPEP § 2117.II.A. And they are "generally understood to be members that can be present in the intestinal microbiota." Ex. 65 ¶¶ 203, 208; *see also* D.I. 265, Ex. 6 at 7:29–33, 7:37–62; Ex. 90 at 201:4–6; Br. 8 ("the human gut microbiome contains . . . virtually all of the classes listed in the Markush group"). They also share a common use: "reconstituting the normal composition of the intestinal microbiota." Ex. 65 ¶ 209; *see* MPEP § 2117.II.B; *In re Harnisch*, 631 F.2d 716, 722 (C.C.P.A. 1980).

Ferring's contrary arguments are divorced from the context of the claims, and the fact the group is claimed at the class level, not the species or strain level. Ferring contends that certain ***species*** or ***strains*** of bacteria that could theoretically be within the claimed ***classes*** of bacteria could "kill humans." *See* Br. 9; Ex. 90 at 96:21–23. But the Markush group describes the bacterial classes present in a "donor's intestinal microbiota," not any bacteria in the abstract. D.I. 262, App'x A ('012 cl. 1, '914 cls. 4, 9). Suggesting a bacterial ***class*** in a human donor's microbiota would include bacterial ***species*** that "kill humans" does not make sense. *See also* Ex. 65 ¶¶ 105, 116–117, 184, 189 (describing screening for pathogens). Also, the ***classes*** of bacteria "must each be considered as a whole and ***should not be broken down into elements or other components***." *In re Jones*, 162 F.2d 479, 481 (C.C.P.A. 1947). The inquiry is whether the "substances grouped have 'a community of chemical or physical characteristics' which justify their inclusion in a common group." *Id.* at 481–82. Here, they certainly do.

Ferring's argument that certain combinations of the bacteria may be "incompatible with the goal of decreasing Proteobacteria" or "increasing Firmicutes" is supported with nothing but attorney argument. Br. 10; *Ferring B.V. v. Barr Lab'ys, Inc.*, 437 F.3d 1181, 1193 (Fed. Cir. 2006)

("attorney arguments are insufficient to overcome a motion for summary judgment"). Regardless, the Court has determined that "active selection" of bacteria is not required (*see* D.I. 145 at 2); rather, the claimed composition represents "a healthy gut microbiota," "without any requirement as to which of the six classes [of bacteria] are present," *see* Ex. 65 ¶ 115.

B. The *Markush*/Relative Abundance Limitations Fully Satisfy Written Description.

Ferring's argument that these limitations "lack written description support" (Br. 10) ignores the context of the claims, the range of descriptions in the specification, and the governing legal framework. The written description requirement is satisfied if a patent's "disclosure allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014) (cleaned up). For genus claims, written description is satisfied if there is "disclosure of ***either*** [1] a representative number of species falling within the scope of the genus ***or*** [2] structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1358 (Fed. Cir. 2019).

The specification explains it is "recognized that the presence of normal, healthy intestinal microbiota (normal gut microorganisms) offers protection against CDI." D.I. 265, Ex. 6 at 2:44–46. It also explains patients with recurrent *C. difficile* had "gut microbiota . . . dominated by members of the Proteobacteria . . . phyla, which normally are only minor constituents of the colon microbiota." *Id.* at 2:44–62. And it explains that transplanting fecal microbiota "allows the fastest reconstitution of a normal composition of colon microbial communities," *id*. at 3:14–17, and further that "post-transplantation samples were dominated by Firmicutes," *id*. at 17:26–28. As one of the named inventors' put it, the inventors sought to create compositions which "***preserve as much as possible*** of what's in" a healthy donor's colon. Ex. 68 at 131:1–132:14.

The claims require a composition comprising a "fecal donor's intestinal microbiota" comprising at least 6 of 10 enumerated bacterial classes. D.I. 262, App'x A ('012 cl. 1, '914 cls. 4, 9). Ferring admits that "virtually all of the classes listed in the Markush group" are contained in the "dominant taxa" of "the human gut microbiome." Br. 8; Ex. 88 ¶ 137 ("***the Markush group . . . claim[s] generally the bacteria . . . in most fecal transplants***"); Ex. 65 ¶ 208. The Markush group reflects the inventors' goal to "preserve as much as possible" the donor's microbiota. Ex. 68 at 131:1–132:14. As the Court previously determined, the claims do not require "active selection." D.I. 145 at 2.

First, the patents describe "structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Ajinomoto*, 932 F.3d at 1358. The claims require an intestinal microbiota comprising at least 6 different classes of bacteria from a group of 10 known bacterial classes. D.I. 262, App'x A ('012 cl. 1, '914 cls. 4, 9). They also provide that, following administration, the relative abundance of certain bacteria is increased ('012 cls.) or reduced ('914 cls). The specification describes the same bacterial classes using the same, well known structural terms that the claims do (e.g., *Bacilli*, *Mollicutes*). *See, e.g.*, D.I. 265, Ex. 6 at 5:25–30. As Dr. Schloss opines, "[n]o part of this pharmaceutical composition is defined by its ***function***. Rather, each element adds a ***structural*** element to the composition." Ex. 65 ¶¶ 99–100. Consistent with that opinion, Ferring admits it understands the well-known structures described in the Markush group. Br. 8 ("[i]t is undisputed that the Markush group is met if there is at least one bacteria present from at least six of the enumerated classes"; Ex. 65 ¶ 60 (bacterial classifications had been well established as of 2011). This admission leaves no doubt that written description is satisfied: the patents describe "structural features common to the members of the genus." *Ajinomoto*, 932 F.3d at 1358.

Second, the patents also describe "a representative number of species falling within the scope of the genus." *Ajinomoto*, 932 F.3d at 1358. Ferring admits that "written description for the % change limitation and the Markush group are in columns 5, 7, and 15 [of the patent]." Br. 11. The Summary of the Invention describes an "embodiment" in which the composition "includes at least . . . ***6*** [or more] . . . different classes of bacteria chosen from [10 enumerated bacterial classes]." D.I. 265, Ex. 6 at 5:25–29.[7] Columns 7-8 also disclose an embodiment with "at least ***6*** classes." *Id.* at 7:67–8:4. Ferring argues these disclosures "do not show that the inventors were in possession of the invention actually claimed" (Br. 11), but that ignores they structurally (not functionally) describe known classes, confirming the inventors possessed the claimed invention.

Ferring's suggestion that Example 1 provides no additional support fails. Example 1 is an embodiment of the claims, Ex. 65 ¶ 185, and "the results of the inventors' sequencing analysis provided in Figures 1 and 2 (the process of which the inventors describe in detail in Example 1) shows that there is a change in the patient's microbiota post-transplantation, as confirmed by the clustering in" Figure 3 and the "text provided with Example 1," *id*. ¶ 188. Ferring's argument, focusing on the legibility of Figures 1 and 2, ignores the full import of the disclosures provided by the accompanying text and other examples and figures in the patent.[8] The specification describes

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[7] While the Summary of Invention also describes a composition with at least 5 classes, disclosure of other embodiments does not detract from the written description of the claimed embodiment. *See Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1369–71 (Fed. Cir. 2022), *vacated on reh'g on other grounds*, 38 F.4th 1013, 1020 (Fed. Cir. 2022) ("disclosure of two other dosages does not detract from the written description of the claimed dose."). The disclosures of the claimed relative increases and decreases in Firmicutes and Proteobacteria (D.I. 265, Ex. 6 at 15:34-49) provides additional support for the same reasons.

[8] Ferring's *Minemyer* case (Br. 11, 12) rejected a priority claim not only because the figures did not pass the "eye" test, but also because there was no other mention of the claim term. *Minemyer v. B-Roc Representatives, Inc.*, 695 F. Supp. 2d 797, 804 (N.D. Ill. 2009). Ferring admits that is not the case here. Br. 11 ("written description for the [limitations] are in columns 5, 7, and 15").

protocols to make and administer the compositions, identify and screen donors, and determine bacterial content pre- and post-transplantation. D.I. 265, Ex. 6 at Examples 1–4, 17:21–29; Ex. 65 ¶ 184. It also explains results obtained from practicing the claimed method, including showing "recipient's post-transplantation samples were dominated by Firmicutes" and "clustered more closely with each other and with the donor sample," D.I. 265, Ex. 6 at 17:20–60. All of these embodiments are representative of the claimed genus, which involves a composition including a "donor's intestinal microbiota" that retains at least 6 different bacterial classes, "allow[ing] . . . reconstitution of a normal composition of colon microbial communities." D.I. 265, Ex. 6 at 3:14–17. The written description requirement is thus independently satisfied because the patents describe a representative number of species.[9]

Allergan USA is nothing like this case. Those claims were ***functionally*** defined (including anything acting as a "filler" and "disintegrant") and the patent's example had "special characteristics" not common to other substances with those functions. *Allergan USA, Inc. v. MSN Lab'ys*, 2023 WL 6295496, at *17 (D. Del. Sept. 27, 2023). *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1341 (Fed. Cir. 2010), likewise defined its genus solely by its function. Here, the claims ***structurally*** describe known classes and the examples do not have "special characteristics."

Finally, written description "is a question of fact," *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991), and the jury must resolve these fact disputes. *Bioverativ Inc. v. CSL Behring LLC*, 2020 WL 1066019, at *2 (D. Del. Mar. 5, 2020) (denying summary judgment);

[9] Ferring argues the claims cover "210 different potential compositions," or perhaps "three billion" or in the "trillions." Br. 13. Ferring's estimates are divorced from the claims, which refer to ***classes***, not ***species*** or ***strains***. Ferring also ignores the context of the claims: the Markush group refers to bacterial classes in a "donor's intestinal microbiota." *E.g.*, D.I. 262, App'x A ('012 cl. 1); Ex. 65 ¶¶ 118, 194–95 ("Ferring's calculations do not reflect a realistic understanding of the possible combinations."); Ex. 64 ¶ 60.

Exelis Inc. v. Cellco P'ship, 2012 WL 6043494, at *8 (D. Del. Nov. 6, 2012) (same).

C. "Extract" Also Has Adequate Written Description Support

The patents provide ample written description support for "extract" as construed, and Ferring's attempt to limit this well-understood term to examples in the specification contravenes substantial precedent. In any event, Ferring's written description argument is untimely. ***First***, while Ferring's final invalidity contentions and expert reports raise numerous § 112 challenge—including other written description arguments—this argument is not included in any of those disclosures. It cannot be "raised for the first time on summary judgment." *Netgear, Inc. v. Ruckus Wireless, Inc*., 5 F. Supp. 3d 592, 618 n.13 (D. Del. 2013).

Second, the Court's construction of "extract" fully satisfies written description. "The standard for satisfying the written description requirement is whether the disclosure allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Alcon*, 745 F.3d at 1190 (citation and quotation marks omitted). The patent contains ample written description support for "extract" as construed, according to its plain and ordinary meaning: "a substance obtained from a material, mixture, organism, or part of an organism by some chemical and/or physical process." D.I. 91 at 60–70; D.I. 148 at 78:25–98:8, 109:9–110:13; D.I. 145 at 2. The patents describe multiple different ways an "extract" can be obtained, including using filtration ***without*** also centrifuging. D.I. 265, Ex. 6 at 13:2–9; *id*. at 13:46–47. And Ferring's expert agrees that "[f]iltration steps can extract material." Ex. 92 at 119:20–21. The foregoing is more than sufficient to allow a POSA to visualize what was claimed.

"[P]atentee[s] can rely on information that is 'well-known in the art' to satisfy written description," and in such cases—as here, with "extract"—the specification requires neither "recitation [n]or incorporation by reference" of materials demonstrating how to achieve the well-known element. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367–68 (Fed. Cir. 2006); *Streck,*

Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1286–87 (Fed. Cir. 2012); *Capon v. Eshhar*, 418 F.3d 1349, 1360–61 (Fed. Cir. 2005). Nor were the inventors "required to describe in the[ir] specification every conceivable and possible future embodiment of [their] invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (sustaining judgment of adequate written description). Here, having described various ways of obtaining extracts, a well-known term, the patents need not describe all possible examples. In contrast, Ferring's only written description case (*MHL Custom, Inc. v. Waydoo USA, Inc.*, 654 F. Supp. 3d 329, 342–45 (D. Del. 2023)) found "***nothing*** in the patent specification to suggest" the (un)claimed "stability" limitation.

Ferring's contortion of witness testimony does not suggest a different results. Dr. Schloss—who provides opinions on ***different*** issues, not "extract"—explained he appropriately read the claims "***in light of***" the specification, not that he was reading limitations into the claims. Ex. 93 at 102:19–104:23; *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1237 (Fed. Cir. 2001). The inventors likewise never limited the claims to extracts achieved through centrifugation as opposed other methods of obtaining an "extract." To the contrary, Dr. Hamilton testified "***I would not say it involves centrifugation***." Br. Ex. 22 at 153:24–154:6.

IV. Summary Judgment of No Infringement of the UMN Patents Would Be Improper

Though Ferring focuses almost entirely on DOE, it also asks for summary judgment of no literal infringement based on just a couple of sentences with essentially no explanation and no mention of differences in the relevant claim language across asserted claims. *See, e.g.*, Br. 20-21. Those undeveloped arguments should be denied for that reason, *SmartGene, Inc. v. Advanced Biological Lab'ys, SA*, 555 F. App'x 950, 954 (Fed. Cir. 2014), but they are also wrong on the merits: Finch has developed substantial evidence of literal infringement of each asserted claim. Ferring is also wrong that summary judgment on Finch's alternative DOE claim is appropriate. It is for the jury to weigh the merits of the parties' competing infringement evidence.

A. Finch Has Adduced Significant Evidence of Literal Infringement

Ferring ignores extensive evidence that the particle size limitations are literally infringed, and improperly lumps materially different claim language together, failing to explain why the specific language of the claims as construed is not met. Br. 21 (arguing "there is an unmet claim ***limitation***"). Finch has adduced significant evidence that REBYOTA literally satisfies the limitations in both types of claims ("***capable of passing through a 0.5 mm sieve***" and "***comprises no particle having a size of greater than 0.5 mm***") and summary judgment must be denied.

"Capable of passing through a 0.5 mm sieve" ('914 patent cl. 7): Ferring argues that "[t]he claims explicitly require that 'no' particle is larger than 0.5 mm. No means none" (Br. 20), but there is no such language in this claim, and Ferring is wrong that this claim precludes any particle size larger than 0.5 mm in the claimed composition. This claim requires a composition that ***comprises***—and therefore, under black letter law, includes ***but is not limited to***—a fecal extract capable of passing through a 0.5 mm sieve. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005). Ferring's experts agree this claim does not preclude particles greater than .5 mm in the composition. Ex. 88, ¶ 174 ("the term means that the fecal suspension ***has minimal material larger than 0.5 mm***"); Ex. 94, ¶ 270. Finch has presented substantial evidence, and there is no dispute, that REBYOTA contains fecal extract capable of passing through a 0.5 mm sieve: REBYOTA is manufactured using a strainer bag with an "approximate 0.5 mm pore size," and "the portion of extract/preparation that passes through the 'approximately 0.5 mm' filter during manufacture is what becomes REBYOTA." Ex. 78, ¶¶ 356, 382. The opinions of Ferring's expert Dr. Johnson likewise show that REBYOTA—post-manufacturing—contains fecal extract capable of passing through a 0.5 mm sieve. Ex. 94, ¶ 211. Summary judgment of no literal infringement must therefore be denied.

"No particle having a size of greater than 0.5 mm" (other asserted claims): Though Ferring

argues that "[t]he claims explicitly require that 'no' particle is larger than 0.5 mm. No means none" (Br. 20), the Court construed this limitation to mean "no particle greater than 0.5 mm ***as shown by sieving***." D.I. 145 at 3. Finch has presented substantial evidence that REBYOTA contains fecal extract with no particle size greater than 0.5 mm as shown by sieving, and Finch disagrees that Dr. Johnson's testing shows otherwise. The manufacturer of the strainer bag used to manufacture REBYOTA describes it as having a "pore size 0.5mm." Ex. 95. And Dr. Benson explains that Ferring told the FDA that the strainer bag used to make REBYOTA has an "approximate 0.5 mm pore size," such that REBYOTA contains no particle greater than the pore size actually used to manufacture the composition and "literally meets this claim element." Ex. 78, ¶ 357. Finch disagrees that Dr. Johnson's testing shows particle sizes greater than 0.5 mm in REBYOTA as shown by sieving. Br. 20. Contrary to Ferring's claim that "Dr. Benson does not rebut Dr. Johnson's showing that larger particles in the accused product would not pass through a 0.5 mm sieve" (Br. 20), Dr. Benson provided rebuttal opinions disagreeing with the way the testing was performed and the conclusions drawn from it. *See generally* Ex. 96, § VI.B; *id.* ¶¶ 97–128 (disagreeing that what Dr. Johnson says remained on the filter in would not pass through if properly oriented, or that particles in clumps would not pass through). At a minimum, these fact disputes are material and must be resolved by the jury. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1371 (Fed. Cir. 2004); *Transcenic, Inc. v. Google, Inc.*, 2014 WL 7275835, at *2 (D. Del. Dec. 22, 2014).[10]

B. Summary Judgment on Finch's DOE Claim Should Also Be Denied

While REBYOTA infringes literally, to the extent the jury improperly credits Ferring's

[10] Though not necessary to resolve here, these claims also use the term "***comprising***" and so do not preclude the composition ***as a whole*** from including any particle greater than 0.5 mm.

questionable, litigation-inspired decision to use the word "approximate" in describing the strainer bag to the FDA,[11] it also infringes under the DOE.

1. Finch's DOE Claim Is Not Barred By Prosecution History Estoppel

Not every claim amendment—even those that "narrow" the claim—results in estoppel of all equivalents. The court must consider whether "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 535 U.S. 722, 740 (2002). Because "[t]he scope of the estoppel must fit the nature of the narrowing amendment," it is necessary to "look to the specifics of the amendment and the rejection that provoked the amendment to determine whether estoppel precludes the particular doctrine of equivalents argument being made." *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010). No estoppel applies to either particle size limitation.

There is no basis to find the estoppel for claim 7 of the '914 patent. Ferring fails to note that, while original claim 54 of the '914 patent recited "said human fecal preparation consists essentially of particles capable of passing through a 0.5 mm sieve," *see* Ex. 97, 11/3/2017 Claims at cl. 54, that claim was ***withdrawn due to an election requirement***. *Id*., 8/2/2018 Remarks at 7. The UMN inventors drafted entirely new claims of wholly different scope than original claim 54, including one that recited a fecal extract capable of passing through a 0.5 mm sieve and also a pharmaceutically acceptable carrier. *Id.*, 8/2/2018 Claims at cl. 71. Cancelled claims were not replaced with dependent claims written in independent form. *Lecat's Ventriloscope v. MT Tool and Mfg.*, 2018 WL 3651592, at *7 (N.D. Ill. Aug. 1, 2018) (no estoppel where newly added claims

[11] *See* Ex. 72, at FER RBX01895073-74 ("One additional point that Lee [Jones, founder of Rebiotix,] reminded me of is that the use of the terminology ["the flexible strainer bag has a pore size of ***approximately*** 0.5 mm through which the product is strained"] is important to ***avoid potential patent infringement issues***.").

"drawn to completely different subject matter than the claims as originally filed"); *Funai Elec. Co. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1369 (Fed. Cir. 2010)); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 610 F. Supp. 2d 370, 385 (M.D. Pa. 2009). Hence, the newly added claim must be considered afresh on its own, and because "[t]hat limitation was never amended" it "cannot be subject to the *Festo* presumption." *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1375 (Fed. Cir. 2003). *Biagro*, where "the reason for the amendment and the asserted equivalent relate[d]" to the claimed limitation, does not apply here. *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005).

No estoppel applies to the other claims either, as the amendments bear no more than a tangential relationship to the equivalent Ferring now attempts to preclude. During prosecution of the parent application (U.S. 9,968,638), patentee amended the claims to recite "no particle having a size of greater than 0.5 mm," Ex. 98, (2/9/2017 Claims) at 2, after which the Examiner maintained the claims as rejected as obvious over Borody (U.S. 9,308,226), explaining a .5 mm sieve cannot distinguish over the prior art as "there are incidences in the prior art literature regarding the fecal extract composition filtered through the 0.5 mm sieve." *Id*., 3/22/2017 Office Action at 3–4, 9–10; *id*., 6/14/2017 Interview Summary. In response, the patentee did not amend the 0.5 mm element, but instead added the Markush group to enumerate specific bacterial classes and specify that non-living material must also be present. *Id*., 6/22/2017 Amendment, cl. 65. The patentee explained that the purpose of these amendments was to capture the need for sufficient non-living material, not to carve out a particular filter size in the abstract. Br. Ex. 37, Applicant Remarks at 11 ("[t]he Examiner has not shown where the cited reference alone or combined ***provide for particles of non-living material***, let alone no particles ***of non-living material*** having a size of greater than 0.5 mm."), 12. The following year, after the examiner rejected the pending claims of the '012 patent

over the same Borody reference, Ex. 99, April 9, 2018 rejection, another examiner then amended the claims (following an interview with the patentee) adding, in part, the very same requirements that were allowed in the '638 patent, including the Markush group, that the fecal extract comprises non-living material, and the particle size element. *Id.*, 12/27/2018 Notice of Allowance at 3–4. Likewise, during prosecution of the '914 patent, the examiner again rejected claims over Borody, Ex. 97, 5/2/2018 rejection, and again, pursuant to the Examiner's suggestion, the same elements were added to the claims. Br. Ex. 33, 8/23/2018 Amendment and Remarks at 2, 7.

The foregoing "strongly indicates that the reason for the amendment[s] was not to cede" a composition including a fecal extract with slightly larger, yet "functionally identical," particles to those claimed. *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1331 (Fed. Cir. 2019); *see also Insituform Techs., Inc. v. CAT Cont., Inc.*, 385 F.3d 1360, 1368 (Fed. Cir. 2004). Rather, while the examiner stated there were a variety of filter sizes disclosed in the art—including a 0.5 mm sieve—UMN explained, and the Examiner found persuasive, that there was no teaching requiring a sufficient amount of ***non-living matter***. This was how patentee distinguished Borody in prosecution of the '638 patent, and the same amendments were made in the '012 and '914 patent. Ferring argues that because the 0.5 mm element was added to the '012 and '914 claims during prosecution, prosecution history estoppel bars *any* DOE argument. But estoppel does not apply where it would "effectively dedicate the entirety of [patentee's] invention to the public," and where the element "would have been irrelevant for distinguishing the prior art." *Eli Lilly*, 933 F.3d at 1334 (finding no estoppel). This is precisely the situation here. Ferring's argument that estoppel must apply "in light of explicit arguments . . . regarding the relevance of the particle size," Br. 18–19, likewise is incorrect. The two passages Ferring cites were from well after the 0.5 mm amendment was made. And the law is clear that amendment-based estoppel and argument-based

estoppel are "[t]wo distinct theories" and, unlike amendment-based estoppel, "[t]o invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter." *Deering Precision Instruments, LLC v. Vector Distribution Sys., Inc.*, 347 F.3d 1314, 1324–26 (Fed. Cir. 2003). Acknowledging the "relevance of the particle size," as alleged by Ferring, is a far cry from "clear and unmistakable surrender."

2. Finch's DOE Claim Is Not Barred By The Doctrine of Claim Vitiation

Ferring's vitiation argument likewise fails. ***First***, Ferring ignores '914 patent claim 7, which does not preclude particles greater than .5 mm in the composition—as Ferring's experts agree (Ex. 88, ¶174; Ex. 94, ¶270)—and the "comprising" language in other claims. Br. 20. ***Second***, Ferring rewrites Dr. Benson's argument—incorrectly alleging he contends that "any size particle can be present." Br. 21. Dr. Benson opined that a composition where *no particle* is greater than 0.5 mm is insubstantially different than one that "has a ***minimal*** number of particles ***slightly*** larger than 0.5 mm." Ex. 78, ¶ 152; *see also* Ex. 100, 180:15–181:19. This is the "appropriate inquiry," as "a reasonable juror could have found" the two to be equivalent in view of Dr. Benson's opinion a POSA would consider them to be. *Bio-Rad Lab'ys v. 10X Genomics Inc.*, 967 F.3d 1353, 1368 (Fed. Cir. 2020).

Ferring suggests that because "[n]o means none," "Dr. Benson's DOE argument effectively eliminates the particle size limitation." Br. 20–21. Ferring ignores not only claim 7 of the '914 patent, but also the Court's construction of the other claims: "no particle greater than 0.5 mm ***as shown by sieving***." As Dr. Benson explains, this construction includes the expected variation in pore size that is inevitable in every filter or sieve. *See, e.g.*, Ex. 78, ¶ 355. "No particle" is not the militant absolute Ferring now proposes. Additionally, Ferring's position that the claim language is diametrically opposed to the equivalent is the precise approach the Federal Circuit has warned against. *Bio-Rad*, 967 F.3d at 1367–68 (cautioning against "using labels like 'antithesis'" rather

than conducting the proper DOE inquiry).

3. Dr. Benson's DOE Analysis Is Entirely Proper

Dr. Benson performed a thorough DOE analysis, using both the "insubstantial differences" and "function/way/result" analysis, focusing on the particle size limitation to which it applies. Ex. 78, ¶¶ 360–363; Ex. 96, ¶¶ 141–152. Dr. Benson explains that "[e]ven if ***there is a small number of particles larger than 0.6 mm***," "it remains true that ***larger chunks of material [have] still be[en] filtered out***, leaving smaller pieces (importantly, to which some bacteria may adhere, and which may provide a nutrient source for the bacteria) and the bacteria themselves, intact." Ex. 96, ¶ 148. Hence, Dr. Benson has properly focused his DOE analysis on the particular element in question, and Ferring's argument that the analysis is "flawed" and focuses on "the claim as a whole" has no merit. Br. 19–20. "An analysis of the role played by each element ***in the context of the specific patent claim***" informs the determination of equivalence. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). It is entirely proper to consider the totality of the particles in the context of the claimed composition, rather than myopically focusing on just the particles in isolation (or as a single particle by itself). Ferring's complaint that Dr. Benson has "no 'hard data'" to support his equivalency arguments (Br. 20) is also factually incorrect (Ex. 78 ¶¶ 362; Ex. 96 ¶¶ 149, 152) and can be explored on cross examination if desired.

V. The Court Should Deny Ferring's Motion of Invalidity of the Finch Asserted Claims Under 35 U.S.C. § 112

The crux of Ferring's argument is straight-forward: because the Court did not adopt its proposal to import the numerical percentages from the specification[12] into the construction of

[12] D.I. 265, Ex. 1 at 7:61–8:2 ("wherein a . . . ([] substantially entire) microbiota is . . . an isolate of fecal flora that is at least about 90%, . . . 99.9% isolated or pure, or having no more than about 0.1%, . . . or 1.0% or more non-fecal floral material"); *id.* at 10:17–24, 13:27–35.

"substantially entire microbiota" ("SEM"), Ferring contends it is indefinite under § 112(b). D.I. 145 at 2; D.I. 148 at 77:3–78:13; Br. 26–30. That is wrong in view of established Federal Circuit precedent and is inconsistent with a POSA's understanding of that term. At a minimum, material fact disputes exist which are for the jury at this juncture.

The law is clear: terms of degree such as SEM are permissible. While "a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty," *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014), "***a patentee need not define his invention with mathematical precision***" to satisfy § 112(b), *Guangdong*, 936 F.3d at 1360 (collecting cases). Instead, a POSA may consult intrinsic and extrinsic evidence—*e.g.*, the specification, prosecution history, and expert opinions—to understand a term of degree, even absent a construction having mathematical limits. *Id.* Guided by those principles, the Federal Circuit repeatedly finds terms of degree not indefinite without importing mathematical limits. *E.g.*, *id.* ("lofty batting" not indefinite); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332–36 (Fed. Cir. 2010) ("not interfering substantially" not indefinite); *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1376–81 (Fed. Cir. 2017) ("visually negligible" not indefinite).

Here, the term "SEM" easily satisfies § 112(b). With respect to the intrinsic evidence, Ferring agrees the specification provides explicit numerical guidance on the objective boundaries of SEM. Br. 27, 28 (citing embodiments with SEM). As Dr. Mazmanian confirms, these passages provide POSAs with more than sufficient guidance of what SEM means. Ex. 101 ¶¶ 119–121. The Examiner relied on these exact passages during prosecution to conclude "SEM" was ***not indefinite without*** requiring that they be imported into the claims—a point Ferring concedes, and which is highly relevant here. Br. 28 ("The examiner's reasoning was ***based on the guidance*** regarding the

numerical ranges . . . .); *Niazi*, 30 F.4th at 1348 ("highly relevant that the examiner understood [the allegedly indefinite] phrase throughout prosecution"); *Guangdong*, 936 F.3d at 1361–62 (similar). And Ferring's experts easily applied the SEM claim language in their validity and non-infringement opinions. Ex. 117 ¶ 235 (applying limitation to prior art); Ex. 94 ¶ 231 (applying limitation to REBYOTA).

While Ferring suggests there is no objective way to determine whether SEM is present without a numerical limit (Br. 26), the Borody patent claims and specification explain how that is done—*i.e.*, by processing raw stool in a manner that preserves as much of the microbiome as possible: starting with raw stool, filtering it in a manner that leaves the fecal flora intact, and adding ingredients that preserve the microbiota during storage. *E.g.*, D.I. 265, Ex. 1 at 11:37–62, 21:12–32, 30:27–57; Ex. 101 ¶¶ 137, 149–152. Under established precedent like *Guangdong*, the claims are definite. Ferring fails to acknowledge this precedent even though Finch raised it during claim construction.[13]

The extrinsic evidence confirms definiteness. While Ferring expresses confusion over SEM, it uses this term to describe REBYOTA. Ex. 102 at FER_RBX01860571 (REBYOTA "capture[s] a '***substantially entire***' healthy ***microbiota*** community"); Ex. 78 ¶ 86 (citing evidence). Consistent with the claims and specification, Drs. Mazmanian and Benson showed how SEM is objectively determined without reference to mathematical limits—*i.e.*, by using a scientifically-grounded, technical assessment of whether a composition's manufacturing process preserves "as much of the microbiota of the stool as possible, as opposed to selecting a small subset of the specific bacterial species to the exclusion of most of the microbiota," Ex. 101 ¶¶ 117–118,

[13] Ferring's case supports Finch. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1259–61 (Fed. Cir. 2014) ("look and feel" and "visually perceptible elements" not indefinite).

149–152, involves steps that would kill off microbiota, and includes steps to preserve the bacteria (like including a cryoprotectant and antioxidant). Ex. 78 ¶¶ 84–88 (analyzing steps Ferring takes to ensure REBYOTA has SEM), 94, 97. Dr. Benson also explains how Ferring's "16s rRNA analysis" provides another objective analysis, as it "demonstrates that Ferring's manufacturing process for REBYOTA 'preserve[s] a level of bacterial diversity consistent with normal feces'" and that "the level of bacterial diversity in RBX2660 provided therapeutic benefit of RBX2660." *Id.* ¶ 89 (quoting Ferring's 16s rRNA analysis). No percentage limits or tests to determine which bacterial strains are present are necessary. *See id.*; Ex. 103 at 124:22–21; Ex. 101 ¶ 117; *see* D.I. 91 at 40.

Ferring does not dispute SEM can be objectively determined through analyses of the manufacturing process at issue. And its claim that a numerical limit is required for definiteness is inconsistent with the science: Dr. Kraft admitted a mathematical limit ***would not be meaningful*** here because there is no way to test for the percentage of microbiota present in the formulation. Ex. 104 at 285:8–19. The upshot is clear: SEM is sufficiently definite, and experts have objective ways to determine infringement. At best, material fact disputes exist on whether a POSA would understand the claim scope with reasonable certainty, requiring denial of this motion. *Eli Lilly*, 845 F.3d at 1371 (for definiteness, "what a [POSA] would understand . . . is a question of fact").

Ferring's primary argument—that Dr. Mazmanian testified that SEM cannot be objectively determined (Br. 26)—is simply incorrect: he repeatedly explained a POSA would determine if the "SEM" term is met by objectively analyzing the manufacturing process used, in full alignment with the intrinsic evidence and Dr. Benson's approach. Ex. 103 at 126:16–127:8, 145:18–146:6, 156:15–158:17. That is not an assessment of "the intent of the putative infringer" as Ferring suggests. Br. 29. That Dr. Mazmanian would not provide "a precise numerical number" is fully

consistent with the authorities, and unnecessary in view of how a POSA determines whether SEM exists.[14]

VI. Ferring's Motion for Non-infringement of Finch Patent Asserted Claims

Ferring contends that it does not infringe three of the four Borody patents because REBYOTA is not for "treating" ('702, '309 cls.) or "sufficient to overcome" ('193 cls.) CDI, based on its contention that REBOYTA is for "preventing" CDI, not "treating" it. Br. 24. But there is no question REBYOTA is for treating CDI, and at best there are material fact disputes. Ferring explicitly confirmed this to the FDA, *i.e.*, that "the efficacy [] for RBX2660 [] was well studied in a robust clinical development program," and that it "demonstrated efficacy ***for the treatment of recurrent C. difficile infection***." Ex. 105 at FINCH_UMN_0015151–52; *see also* Ex. 106 at FER_RBX00210382 (Ferring clinical study titled "A Phase 2 Open-Label Clinical Trial Demonstrating the Safety of [REBYOTA] (microbiota suspension) ***for the Treatment of Recurrent Clostridium difficile-associated Diarrhea"*** reporting 87.1% efficacy); Ex. 107 ¶ 85 (collecting citations, including paper stating "***RBX2660 treatment*** was consistently efficacious and safe in older adults with rCDI and common comorbidities"); Ex. 108 at 601 ("FMT continues to be widely used ***for the treatment of recurrent CDI***."); Ex. 109 at 1529 "("RBX2660 is effective and safe ***in treating patients with recurrent CDI.***"). And both sides' experts confirmed that FMT compositions such as REBYOTA are for treating CDI. Ex. 104 at 145:19–146:22 (Ferring's expert Dr. Kraft: "I would agree with Dr. Stollman" that "Rebyota is in an amount effective for treating

[14] Dr. Mazmanian's testimony on what percentages could qualify as SEM are not contradictory. Despite Ferring's repeated attempts to get Dr. Mazmanian to place a numerical limit on the claims, he was clear that is not the way to assess SEM; analyzing the manufacturing process is. Ex. 103 at 125:6–21, 126:16–127:8. His testimony that a composition would need more than 50% of the microbiota for SEM (Br. 29) is consistent. And contrary to Ferring's assertions, Dr. Mazmanian never testified that a composition with 10% of the microbiota would qualify as SEM. Ex. 103 at 131:22–132:20.

recurrence of C. difficile infection" "[b]ased on the results of these clinical trials"); Ex. 110 at 205:17–206:22 (Ferring's expert Dr. Polage admitting his paper reports for REBYOTA an "87.1 percent success rate" "to treat CDI"); Ex. 111 at 16:21–17:12 ("[REBYOTA] is a treatment for recurrent C. difficile"); Ex. 107 ¶¶ 67–68; Ex. 112 § 7(b). That makes sense: as confirmed by fact and expert witnesses and other evidence, the patented FMT compositions are administered ***after*** a patient contracts CDI, and are used to put an end to that condition in patients. D.I. 265, Ex. 2 at 3:50–63; Ex. 69 at 237:12–238:3 ("We don't see the patients prior to getting C. difficile"); D.I. 265, Ex. 6 at 20:25–27 (inclusion criteria includes a history of "symptomatic, toxin-positive infection by *C. difficile*"); Ex. 113 at FER_RBX02700278 (REBYOTA label indicating patients in clinical trial had "confirmed" diagnosis of rCDI); Ex. 112 ¶ 50 (REBYOTA is administered "specifically and solely to patients diagnosed with *C. difficile*").

Ferring's sole evidence on this point is that the REBYOTA label states that it is "not indicated for treatment of CDI." Br. 24. But that statement is explicitly contradicted by Ferring's statements to the FDA, its experts and other materials. Ex. 114 at 341:24–346:7; Ex. 106 at FER_RBX00210382; Ex.108; *see supra*. While Ferring relies on the ACG guidelines' reference to FMT under the heading of "Prevention of CDI Recurrence," (Br. 24–25) it omits that the guidelines explicitly confirm FMT (and REBYOTA) is a treatment of rCDI. Ex. 112 ¶ 46 ("FMT, as previously discussed, is considered to be the best ***treatment option for multiply recurrent CDI***" and "prevention of recurrence" is "part of rCDI treatment"); *see also* ¶¶ 47–48 (IDSA Guidelines describing FMT under the heading "What are the best treatments for recurrent CDI?"). Ferring's arguments concerning the use of "prevention" and "treatment" in the specification and file history (Br. 25) are similarly irrelevant: the claims require "treatment" of CDI, and the evidence repeatedly confirms that REBYOTA meets that requirement. And Dr. Stollman confirmed that "proper

treatment of CDI (*i.e.*, through FMT as described in the Finch patents) will also *prevent future occurrences* of the disease" (Ex. 112 ¶ 41); Dr. Polage agrees that these terms are not mutually exclusive (Ex. 110 at 135:11–16); *see also* D.I. 265, Ex. 2 at 10:56–65. And Ferring does not explain why, with respect to the '193 patent claims, REBYOTA is not "sufficient to overcome" CDI, nor could it: Ferring's trial results establish that REBYOTA has been shown to overcome CDI—a fact that both sides' experts agree on. Ex. 107 ¶¶ 107–109; Ex. 78 ¶¶204–206. At a minimum, material fact disputes exist. *Transcenic*, 2014 WL 7275835, at *2 ("the issues presented by Google's summary judgment motions present a 'battle of the experts' that is not amenable to resolution prior to the presentation of evidence, including testimony."); *AFG*, 375 F.3d at 371 ("a trial court cannot reach a conclusive finding of noninfringement if the record shows some evidence supporting a finding of noninfringement and some evidence to the contrary.").

VII. The Finch Patents' Asserted Claims are Patent-Eligible Under 35 U.S.C. § 101

With barely a reference to a single claim element, Ferring asks the Court to find clear and convincing evidence that all Borody asserted claims are ineligible. That is a high bar, particularly at summary judgment. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). Ferring's request is baseless and should be denied.

Prior to Dr. Borody's inventions, FMT was a rudimentary procedure that involved collecting samples of human stool and crudely processing them in a colonoscopy suite for near-immediate administration. D.I. 262 at 4. This approach had major drawbacks, including that it required malodorous in-office, one-off FMT preparations by physicians, and produced formulations with little to no shelf life. *Id.*; Ex. 115 ¶¶ 19–20, 30; Ex. 64 ¶¶ 9, 26. Dr. Borody's inventions overcame these hurdles by including properly-gauged processing steps and incorporating specific, unconventional ingredients that gave the formulations "prolonged life" so that they could be centrally manufactured, stored, and shipped as ready-to-use products "to distant

hospitals." D.I. 265, Ex. 2 at 30:26–36; *id.* at 17:39–41, 28:55–29:33; 30:49–52, 30:65–31:17; *see* D.I. 262 at 4. These inventions revolutionized the FMT space, providing patients access to FMT products that physicians previously refused to prepare on their own. Ex. 64 ¶¶ 25–30; Ex. 115 ¶¶ 19–30, 38–41.

A. The Asserted Claims Are Patent-Eligible Under Step One

Alice step one requires an assessment of what the claims are "directed to," being "careful to avoid oversimplifying the claims." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016). Here, the asserted claims are directed to new and useful enema products/systems containing pharmaceutical compositions produced by the novel processing of fecal samples plus special additives such as a cryoprotectant and an antioxidant to preserve viability for transport to a remote facility. D.I. 262, App'x A. These features are found in every asserted claim and are repeated throughout the specification. *E.g.*, D.I. 265, Ex. 2 at 21:54–22:5, 30:49–52, 31:4–15. Ferring ignores these clear requirements, artificially contending that the claims are directed to naturally occurring substances (*e.g.*, "fecal bacteria," "fecal flora"), or generic prior art compositions ("a human fecal microbiome preparation"). Br. 31–32. None of these are capable of producing the patented ***improvements***, and Ferring's ends-driven overgeneralization fails to "articulate what the claims are directed to with enough specificity to ensure the step one inquiry is meaningful." *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1346–49 (Fed. Cir. 2017).

Regardless, Finch's claims easily satisfy step one. ***First***, the "claims [that] include physical process steps that change the composition of the mixture" from its naturally-occurring counterpart are patent-eligible. *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319, 1326 (Fed. Cir. 2020) (claims to a method for preparing a fraction of cell-free DNA enriched in fetal DNA held eligible); *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1350 (Fed. Cir. 2019) ("We do not see . . . how a claim to the manufacture of a non-natural supplement would be directed to . . .

[a] natural product."). Here, the claims ***combine*** a cryoprotectant, an antioxidant, or both with stool, resulting in an "improved end product that is more useful" than stool itself for treating CDI. *Illumina*, 967 F.3d at 1326; D.I. 262, App'x A. ***All experts agree*** that: (i) the claimed cryoprotectants protect the cells in the compositions from ice crystal formation that would otherwise cause them to burst when frozen and thawed. D.I. 265, Ex. 2 at 21:54–67; Ex. 111 at 92:15–93:13, 106:1–10; Ex. 101 ¶¶ 50–51, 58; Ex. 116 at 136:20–137:8; Ex. 117 ¶ 45; Ex. 104 at 67:13–68:12; Ex. 100 at 185:17–22; Ex. 64 ¶ 61; Ex. 78 ¶ 88, 132, 186, 192; Ex. 96 ¶ 37; and (ii) antioxidants protect anaerobic fecal flora during storage by preventing cell death due to oxygen exposure. *E.g.*, D.I. 265, Ex. 2 at 30:49–52, 31:4–15; Ex. 111 at 84:12–20; Ex.101 ¶¶ 65–68; Ex. 116 at 132:11–133:9, 164:16–24; Ex. 78 ¶ 174; Ex. 96 ¶ 37; Ex. 118 ¶¶ 48–51. The PTO recognized this eligibility indicium, which Ferring fails to address. Ex. 119 at FINCH_UMN_0005687. Ferring fails to address this indicium of patent eligibility.

Second, the claimed compositions have markedly "different characteristics [from the natural product] and 'the potential for significant utility.'" *Nat. Alts.*, 918 F.3d at 1348 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)). Unlike stool, the patented compositions include specific ingredients allowing them to be frozen and transported to hospitals where they are later thawed for administration, overcoming significant problems with prior art treatments. D.I. 265, Ex. 2 at 21:54–22:5, 30:26–36, 31:4–15; Ex. 101 ¶¶ 59, 64–68, 79, 81, 108–111; Ex. 116 at 137:21–138:12; Ex. 117 ¶ 205; Ex. 120 at MERRIFIELD00000708; *Nat. Alts.*, 918 F.3d at 1348 (compositions "increase[d] athletic performance in a way that naturally-occurring beta-alanine cannot"); *Chakrabarty*, 447 U.S. at 310 (modified bacteria eligible); *Ass'n Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590–95 (2013) (synthetic cDNA eligible).

Ferring's assertion that Finch introduced "no evidence or testimony" that (Br. 31–32) is

therefore wrong. And Ferring itself persuaded the PTO that claims requiring "a cryoprotectant" were patent-eligible because the compositions "reduced susceptibility to damage from freezing ***by virtue of the presence of the added cryoprotectant***" and therefore were "***markedly different*** from any naturally-occurring corollary." Ex. 121 at FINCH_UMN_0028018–019; Ex. 122 at 9; *see* Ex. 111 at 142:9–24; Ex. 104 at 85:10–18; Ex. 121 at FINCH_UMN_0028086.

Purported "undisputed evidence" that "even when no cryoprotectant is used, an amount of fecal flora effective for preventing rCDI remains in the stool extract" (Br. 31) is irrelevant. Dr. Borody recognized the need for more, introducing a cryoprotectant to ensure that substantially all the bacteria survive and achieve other benefits. D.I. 265, Ex. 2 at 22:1–5. And "cryoprotectants" aside, Ferring does not dispute that antioxidants render the patented composition "markedly different."[15] ***Third***, Ferring disregards the specific, non-abstract claim elements requiring a container containing the composition for direct enema delivery, which provide a ready-to-use composition suitable for transport to a remote facility. D.I. 262, App'x A ('702, '309, '080 cls.). ***Fourth***, the there is no preemption concern here. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). Ferring's experts agree that the claims reflect only a subset of the numerous FMT approaches that can be used to treat *C. difficile*, *e.g.*, via different routes of administration (oral, nasogastric, Ex. 117 ¶¶ 54, 228) or using different formulations (*e.g.*, without a cryoprotectant or antioxidant, *see* Br. 35).

B. The Asserted Claims Satisfy Step Two

The claims "involve more than performance of well-understood, routine, [and]

[15] Ferring's reliance on *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280 (Fed. Cir. 2023) is inapposite. Br. 32. Unlike in *ChromaDex*, where the claims broadly "read on milk" and simply ***isolated*** milk protein "compared to how it naturally exists," 59 F.4th at 1283–84, none of the Borody merely isolate "fecal flora." *See supra.*

conventional activities previously known to the industry." *Berkheimer*, 881 F.3d at 1367–68 (step 2 is "a question of fact"). Here, prior art FMT preparations involved crudely processed stool in a colonoscopy suite for near-immediate administration to patients. In contrast, the claimed compositions include specific ingredients allowing for the storage, shipment, and use as described above—none of which was "well-understood, routine, or conventional" in 2011. ***First***, the evidence confirms there was significant uncertainty over whether cryoprotectants could preserve complex microbiomes, like that of the human gut, without affecting bacterial viability. *E.g.*, Ex. 101 ¶ 77; Ex. 64 ¶¶ 16–19, 194, 276; Ex. 111 at 179:25–180:7, 180:23–181:1; Exs. 123, 124 (Judy Berman referring Mr. Hlavka to UMN inventors for advice on freezing bacteria because it was "difficult to know if [the good bacteria] survive the freeze/thaw").[16] ***Second***, the use of an antioxidant in FMT was not known in the art, a fact the PTO recognized. Ex. 101 ¶ 80; Ex. 64 ¶¶ 117–118; Ex. 117 ¶¶ 301–302. ***Third,*** Ferring ignores numerous other key elements, including delivery directly from the enema bag, for ease of transport and use. The patented inventions also had a real-world impact: they provided a first-ever means to store FMT treatments for prolonged periods, making stool banking a reality and allowing broad access to ready-to-use products. *E.g.*, D.I. 265, Ex. 2 at Example 1; Ex. 64 ¶¶ 25–30; Ex. 115 ¶¶ 19–30, 38–41; Ex. 101 ¶ 111 & n.3. Ferring repeatedly touts the same unconventional benefits in REBYOTA, confirming that its knock-off process will "solve the problems of [fecal transplant therapy] by creating a ready-to-use, off-the-shelf product that the doctor can order as needed." Ex. 120 at MERRIFIELD00000707; Ex. 125 at FER_RBX02330722–723 (competitive advantage of

[16] This was particularly true for the claimed "PEG" cryoprotectant, which is a known ***laxative*** and ***antimicrobial agent*** (Ex. 64 ¶¶ 20–21, 1366–70), making it counterintuitive to add to FMT products, which rely on the ***viability of bacteria*** to treat ***chronic diarrhea***—a point Ferring itself emphasized during prosecution of its own patents, *id.* ¶¶ 1366–70.

REBYOTA is it is a "'ready-to-use' product with significant shelf-life stability vs. traditional FMT"; it "upgrades FMT"); Ex. 126 at BERMAN00007559 (promoting REBYOTA as having "[s]ignificant product inventory shelf life"); Ex. 127 at FER_RBX02022148 (similar).

Ferring's responses are unavailing. Ferring's reliance on filtration/homogenization steps in isolation (Br. 32–33) fails to account for the claim elements ***as a whole***. *Alice*, 573 U.S. at 218. Ferring's criticism of Dr. Mazmanian's testimony on how the claimed cryoprotectants function in an FMT composition (Br. 33–34, 36) are wrong and conflict with its own experts' testimony. Similarly, it is "undisputed" that cryoprotectants and antioxidants are unnecessary for preserving clinical efficacy. Br. 35. Ex. 101 ¶ 58 ("[A]ddition of a cryoprotectant is expected to ***enhance*** efficacy of a FMT by ***increasing the viability of bacteria*** in the stool."); Ex. 116 at 136:20–138:12. It also is irrelevant, as it fails to address whether adding those ingredients is routine and unconventional. Ferring's assertion that the claims have no "threshold" or "effective" amount of the claimed ingredients (Br. 35–36) is wrong— the experts ***agree*** POSAs would ***not*** add only a "de minimis" amount of either ingredient. Ex. 111 at 47:10–49:1; *see* Ex. 101 ¶ 78. That Dr. Borody overcame a rejection in the prosecution of another patent not at issue here by requiring an "effective amount" of those ingredients (Br. 34) is irrelevant in view of those uniform opinions. And that certain claims do not expressly require freezing or a particular amount of viable fecal flora viable (Br. 35) is also irrelevant, since all claims require a cryoprotectant (and some require an antioxidant). At a minimum, Ferring's arguments present material fact disputes, and its motion should be denied.

VIII. The Court Should Deny Ferring's Motion to Exclude Malackowski's Opinions

Ferring asks the Court to exclude Malackowski's opinions based on its cross-examination, but that is not *Daubert*'s purpose. The motion ignores Malackowski's analysis and binding Federal Circuit precedent. Courts routinely find analyses like Malackowski's, which rely on *Georgia-*

Pacific and the hypothetical negotiation, pass muster. Specifically, Malackowski analyzed Finch, Ferring, and industry agreements, which included rights to the patents-in-suit or comparable technology. Ex. 128 at 12:5-10, 18:5-20:1. Finch's technical expert, Benson, opined on the comparability of the technology in the Seres-Nestlé license and the Rebiotix-Ferring merger, which Ferring does not challenge. Ex. 78 ¶ 25. Nearly all Malackowski's analyzed agreements had the same structure: upfront payment and running royalty, Ex. 129 at 6–7; Br. Ex. 8 at 39:10–40:8, 42:10–43:2. And the REBYOTA acquisition included this structure. Ex. 129 at 56–57. The upfront and royalty payments were for making, using, and selling practicing products, and several agreements granted exclusive/co-exclusive rights. Ex. 129 at 43–45, 47–48, 50–51, App. 6.1.

Malackowski determined that the Seres-Nestlé license was the most comparable because it relates to the use of FMT to treat *C. diff.*, is co-exclusive, is between sophisticated parties, has built in apportionment through dividing consideration between an upfront payment, running royalty, and milestone payments, and has mutual cost-sharing obligations that apportion out economics outside Finch's asserted patents. Ex. 128 at 13:2–18. He apportioned the $175 million upfront payment to exclude know-how and to account for Ferring's position ($51.5M to acquire Rebiotix) and Finch's position (it spent more than that to develop its product). *Id.* at 14:10-15:17. Considering these facts and the industry median upfront payment of $102M, Malackowski concluded that the parties would reach a $50M upfront payment. *Id.* Malackowski also apportioned the Seres-Nestlé license's running royalty to exclude know-how and to account for Ferring's position ([redacted]) and Finch's position ([redacted]). *Id.* at 78:8-79:9. Because of these facts and the industry's 30% running royalty median Malackowski concluded that the parties would have agreed to a 30% running royalty. *Id.* Malackowski further apportioned the upfront payment and running royalty by

patent family based on Benson's analysis that the asserted patent families have equally important technical value to REBYOTA. Ex. 129 at 5–6. Malackowski further reduced (from Benson's calculation of the percentage of patients that meet the claim elements) the base for two UMN patents. *Id.* The Federal Circuit has approved of damages with lump sum and running royalty components. *Fujifilm v. Benun*, 605 F.3d 1366, 1373 (Fed. Cir. 2010). Credibility and factual disputes are for the jury. *Summit 6 v. Samsung*, 802 F.3d 1283, 1299 (Fed. Cir. 2015).

A. The Upfront Royalty Is Tied to Infringement/Comparable Agreements

Neither of Ferring's arguments has merit. ***First***, Ferring contends that Malackowski's opinion is improper because it would be paid even if there were no "infringing sales." Br. 36–37. But there *are* infringing sales since January 2023. Regardless, there is no rule (and *Aqua Shield* does not say) that a royalty can be awarded only if there are "infringing sales." Rather, "[t]he 'value of what was taken'—the value of the use of the patented technology—measures the royalty." *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014). The value of that use (whether making, using, selling, offering for sale, or importing) can be measured in a variety of ways, including through comparable licenses. *Summit 6*, 802 F.3d at 1296. The Federal Circuit's opinion in *Transocean v. Maersk*, 699 F.3d 1340 (Fed. Cir. 2012), is instructive. The Federal Circuit explained that a "reasonable jury could conclude that at the time [defendant] first infringed by offering a dual-activity rig for sale, the parties would have negotiated a license granting [defendant] the right not only to offer the rig for sale, but also to deliver a rig that uses [patented] technology" because the patentee's "proposed royalty of a $10-15 million upfront payment and a five percent running royalty assumes that the license grants [the defendant] 'unfettered' future use of the licensed patents." *Id.* at 1359. A jury could reach the same conclusion based on Malackowski's opinions. As Malackowski explained, the hypothetical license here would give Ferring the ability to use the patented technology to generate sales. The licenses Malackowski

relied on provide that in exchange for such rights, licensees typically pay an upfront payment and a running royalty. Ferring itself used that this very payment structure for REBYOTA. Ex. 129 at 57–59. As the Seres-Nestlé license makes clear, the upfront fee is for rights to make, use, and sell a product practicing patents, which is precisely what Ferring is doing. *Id.* at 63–64.

Second, Ferring disagrees that the Seres-Nestlé license or Ferring merger agreements are sufficiently comparable. Although "there must be a basis in fact to associate the royalty rates used in prior licenses to the particular hypothetical negotiation at issue," *Uniloc v. Microsoft*, 632 F.3d 1292, 1317 (Fed. Cir. 2011), the Federal Circuit has "never required identity of circumstances." *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1330-31 (Fed. Cir. 2014). An expert can rely on licenses that do not include the patent in suit as long as accounting for technological/economic differences. *Wordtech v. Integrated*, 609 F.3d 1308, 1320 (Fed. Cir. 2010). That is exactly what Malackowski did. Ex. 129 at 38–66. Moreover, commercial collaborations are the industry norm, Ex. 128 at 153:10–154:4, and Putnam offers zero comparable, bare patent licenses, *id.* at 153:17–154:4; *Amgen Inc. v. Sanofi*, 2016 WL 675576, at *2 (D. Del. Feb. 18, 2016). "[T]he degree of comparability . . . are factual issues." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012) (agreements not involving patents in suit); *Bio-Rad*, 967 F.3d at 1374 (similar technology met baseline).

For the Seres-Nestlé license, Ferring claims that Malackowski could not establish technical comparability because he did not know whether the Seres product embodied the asserted patents and the licensed patent numbers are redacted. Br. 38. Technical comparability does not require that a license cover the asserted patents or infringing products. Rather, it is enough for an expert to compare the license technologies to the asserted patents. *First Quality Tissue, LLC v. Irving Consumer Prods. Ltd.*, 2022 WL 958089, at *16-17 (D. Del. Mar. 30, 2022); *Ericsson, Inc. v. D-*

Link Sys., Inc., 773 F.3d 1201, 1227 (Fed. Cir. 2014). Benson, not Malackowski, established the technical comparability of the Seres-Nestlé agreement, and Benson concluded that "[t]he 2021 Seres-Nestlé Agreement concerns Nestle's license to Seres patents and know-how for purposes of producing FMT C. diff treatments," which Ferring does not challenge. Ex. 78 ¶ 25. Putnam even opines that this Seres-Nestlé collaboration was more of a market threat to Finch. Ex. 130 ¶¶ 30, 97. And although Ferring claims it is not clear what patents are in the Seres-Nestlé license, that is neither correct nor relevant. The license defines the covered patents as patents that Seres or its affiliates control, that cover any licensed product or the commercialization thereof, and that cover inventions that are necessary or useful for commercialization of SER-109. Br. Ex. 55 at -9906, -9918, -0059. Regardless, Ferring does not dispute the license relates to FMT *C. diff.* patents and technology or that such treatments are technically comparable, and none of Ferring's cases exclude damages expert testimony based on technically comparable licenses. *See LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 79-80 (Fed. Cir. 2012); *ResQNet v. Lansa*, 594 F.3d 860, 870 (Fed. Cir. 2010); *TV Interactive v. Sony*, 929 F. Supp. 2d 1006, 1016 (N.D. Cal. 2013). Further, Malackowski explained why the "profit-sharing" provision in the Seres-Nestlé license operates like a running royalty. Br. Ex. 8 at 86:15–24 ("Profits" is "[e]ssentially net revenues less true-ups for allowable expenses," so "[i]t's closer to a royalty than a profit sharing."). Malackowski further explained that this structure "places downward pressure on the hypothetically negotiated royalty." Ex. 129 at 65. Accordingly, the Seres-Nestlé license is sufficiently comparable, and Malackowski accounted for differences, *Id.* at 62–66, making this an issue for cross, *BASF Plant Sci. v. Commonwealth Sci. and Indus. Rsch. Org.*, 28 F.4th 1247, 1277 (Fed. Cir. 2022).

And the Rebiotix-Ferring merger does inform the parties' hypothetical negotiation positions, and demonstrates that Ferring would have considered an upfront payment and running

royalty for REBYOTA. *See Finjan Inc. v. Blue Coat Sys., Inc.*, 2015 WL 4129193, at *4 (N.D. Cal. July 8, 2015). Benson opined that the agreement covered REBYOTA. Ex. 78 ¶ 25. That more than meets the requirements of technical comparability. *Vectura v. Glaxosmithkline*, 981 F.3d 1030, 1041 (Fed. Cir. 2020); Ex. 128 at 14:10–21, 73:8–21, 156:24–157:10. This agreement demonstrates Ferring's willingness to make an upfront payment for a product that had market uncertainties and risks. Ex. 131 at 44–45. And Ferring's expert relies on the merger, Ex. 132 at 141:25–142:21, so it cannot prevent Malackowski from doing the same. *Versata v. SAP*, 717 F.3d 1255, 1268 (Fed. Cir. 2013).

B. The Exclusivity Of Rights Is A Factual Dispute

Exclusivity is a *Georgia-Pacific* factor, Br. 40, and none of Ferring's cited case (*Aqua Shield*, 774 F.3d at 772 (error to cap royalty at profits); *Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1447 (Fed. Cir. 1990) (error to rely on single license as "established royalty"); *Georgia-Pac. Corp. v. U.S. Plywood Corp*., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (not relying on licenses)) exclude an expert for opining that the hypothetical license is exclusive. To the contrary, courts have permitted experts to opine that the hypothetical license would be exclusive. *AngioScore, Inc. v. TriReme Med., Inc.*, 2015 WL 5258786, at *7 (N.D. Cal. Sept. 8, 2015). Nearly all the licenses for comparable technology are exclusive or co-exclusive, Ex. 129 at 47, 63, and Finch withdrew from the FMT market in January 2023 [redacted]. Ex. 131 at 14. Regardless, this issue does not impact the royalty amount; it was simply a consideration. Ex. 128 at 13:2–15:17, 78:8–79:9.

C. Malackowski's 30% Running Royalty Is Apportioned

Ferring quotes case law and asserts without explanation that Malackowski's royalty rate is not apportioned. Br. 40. This conclusory argument is waived, and this ground should be denied without further consideration. D. Del. R. 7.1.3(c)(2); *Edgewell Personal Care Brands, LLC v.*

Albaad Massuot Yitzhak, Ltd., 2017 WL 1900736, at *4 (D. Del. May 9, 2017). Malackowski did apportion his royalty rate for the value of the patented technology, and Ferring's disagreement with the degree of apportionment is a matter for cross-examination. Ex. 128 at 78:8–79:9; Ex. 129 at 5–6. As explained above, Malackowski's royalty rate is based on the Seres-Nestlé agreement, which he concluded is technically and economically comparable and apportioned to account for know-how, the parties' positions, and Benson's opinion that the asserted patents are substantially responsible for REBYOTA's value. Ex. 129 at 5–6; *see AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339-40 (Fed. Cir. 2015). Malackowski's opinion, therefore, is proper. *Ericsson*, 773 F.3d at 1227. And Ferring's cited authority is inapplicable. *Bio-Rad v. 10X Genomics, Inc.*, 2018 WL 4691047, at *8 (D. Del. Sept. 28, 2018) (built-in apportionment predicates not established); *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Group LLC*, 879 F.3d 1332, 1349 (Fed. Cir. 2018) (no apportionment explanation); *First Quality*, 2022 WL 958089, at *12 (expert had not apportioned at all); *Roche v. Meso*, 30 F.4th 1109, 1123 (Fed. Cir. 2022) (court did not reach damages issues).

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